



**UNITED STATES DEPARTMENT OF COMMERCE  
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Ca

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/831,720	05/14/01	CASELLAS	P IVD 1087

027546  
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HM12/0725

EXAMINER

OZGA, B

ART UNIT	PAPER NUMBER
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1651

4

DATE MAILED: 07/25/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/831,720

Applicant(s)

CASELLAS ET AL.

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 16-38, drawn to compositions and methods for treating cutaneous stress, classified in class 424, subclass 401.
- II. Claims 39-41, drawn to microorganisms, classified in class 435, subclass 252.1.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably unrelated, one is a composition, the other microorganisms.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Paul Dupont on 7/19/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 16-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 17, 26, 27 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ormfa et al. (J. Ital. Derm., vol. 45, no. 5, pp. 325-9, 1970)

The instant application claims a topical composition for treating cutaneous stress containing as active principle a substance that binds to the peripheral benzodiazepine receptors. It also claims methods for the treatment of cutaneous stress which comprises topically administering to a subject in need of such treatment an effective amount of a substance that binds to the peripheral benzodiazepine receptor.

Ormfa et al. teach alcoholic solutions of Nobrium (a derivative of a benzodiazepine). They also teach a topical composition for treating various dermatological disorders (including cutaneous stress) containing as active principle a substance that binds to the peripheral benzodiazepine receptors. They also teach methods for the treatment of cutaneous stress which comprises topically administering to a subject in need of such treatment an effective amount of a substance that binds to the peripheral benzodiazepine receptor. (See p. 325, fifth paragraph, left column)

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy (*A Psychosomatic Approach to the Management of Recalcitrant Dermatoses* 4(6), Nov. 1963, 334-7).

The instant application claims the active principle as .001% to 10% by weight of the total composition weight.

Levy teach 2.5-10 mg of diazepam (p. 336, third paragraph) as the active principle, which comprises between .001-10% of the total weight of the composition.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ormfa et al in view of Levy and Bloom et al. (US 5614178).

The instant application claims a composition wherein the substance that binds to the peripheral benzodiazepine receptor (PBR) is RO 5-4864, a method of treatment of cutaneous stress by administering an effective amount of the above substance and a method for reducing wrinkles which comprises topically

administering an effective amount of a substance produced by fermentation that binds to the peripheral benzodiazepine receptor.

Ormfa et al. teach alcoholic solutions of Nobrium (a derivative of a benzodiazepine). They also teach a topical composition for treating various dermatological disorders (including cutaneous stress) containing as active principle a substance that binds to the peripheral benzodiazepine receptors. They also teach methods for the treatment of cutaneous stress which comprises topically administering to a subject in need of such treatment an effective amount of a substance that binds to the peripheral benzodiazepine receptor.

While Ormfa et al. and Levy do not expressly teach RO 5-4864, they do teach diazepam, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use chlorodiazepam, instead of diazepam because of structural similarity, unless a showing of unexpected results can be established.

Also, while Ormfa et al. and Levy also do not expressly teach a fermentation product, however, since it is the product itself and not the method of obtaining said product that is claimed, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a fermentation

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product instead of a synthetic molecule, since the end result, an active principle that binds to the PBR, is the same.

Ormfa et al. and Levy do not teach hydroxy acids or retinoic acid as an additional ingredient in a composition for treating cutaneous stress.

Bloom et al. teach hydroxy acids and retinoic acid as an ingredient in a composition for treating cutaneous stress. (See Col. 5, lines 7-14.)

In light of the ingredients all having been taught as being useful for treating cutaneous stress, it would have been prima facie obvious to combine previously known compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a new composition to be used for the very same purpose (In re Kerkhoven, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA, 1980)).

Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the compositions and processes as recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

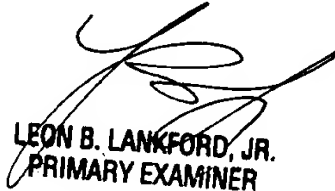
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO  
July 19, 2001

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER